

U.S.S.N. 09/621,092

Filed: July 21, 2000

**AMENDMENT AND RESPONSE TO OFFICE ACTION****Remarks**

Claims 28-30, 41 and 43-45 are pending. Claims 41 and 44 have been amended. Claim 42 has been canceled.

The present invention is unit dose capsules for use in a dry particle inhaler. Claim 41 has been amended to require a keying surface to orient the capsule within the inhaler. Claim 44 has been amended to further require a keying surface to identify the drug within the inhaler.

**Rejection Under 35 U.S.C. § 102**

Claims 30 and 41-45 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,632,971 to Yang. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The elements of claim 41 are:

- (1) a capsule for use in an inhaler
- (2) comprising a keying surface to orient the capsule in an inhaler.

The prior art does not disclose either element. Therefore the prior art does not anticipate the claimed subject matter.

***U.S. Patent No. 5,632,971 to Yang***

Yang describes an empty medicinal capsule including a cap member containing a cap circumferential slot (3') and at least one raised member disposed on the inner surface thereof, and a body member containing a body circumferential slot (3), whereby the cap member circumferential slot and the body member circumferential slot can be slidably locked with each

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other. A plurality of raised triangular slots (7) formed on the inner surface of the cap member prevent final locking of the capsule when in a prelocking state and prevent the separation of the cap and body members once the capsule is in a final locking state. Yang discloses a medicament capsule with raised members and slots which orient the top portion of the capsule with the bottom portion of the capsule. Yang does not suggest the use of this capsule in an inhaler which is specifically fitted for the medicament capsule. *Indeed, there is no mention of an inhaler in Yang.*

Claim 41 defines a capsule (1) to contain drug for use in an inhaler comprising (2) a keying surface on an outside surface of a closed end of the capsule that is (a) adapted to orient the capsule within the inhaler or (b) identifies the drug to be placed in the capsule. Claim 30 defines the capsule of claim 41 further including a medicament.

The Examiner considers slots 3' and 7 to be keying surfaces. Yang clearly states that the triangular slots (7) are disposed on the *inner* surface of the cap member (col. 3, lines 32-34). Therefore, interior slots (7) cannot be used to orient the capsule within an inhaler. Furthermore, as discussed above, cap circumferential slot (3') is not a mechanism to orient the capsule within an inhaler, but rather a means of locking the top portion of the capsule to the bottom portion of the capsule (col. 4, lines 4-7). However, since the Examiner considers slots 3' and 7 to be keying surfaces, claim 41 has been amended to reflect that the keying surfaces are found on the outside surface of the closed ends of the capsule. Support for this amendment can be found on page 11, lines 14-18 and in Figure 7.

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Yang does not disclose a capsule to contain medicament for use in an inhaler with keying surfaces on the outside surface of the closed ends of the capsule. The term 'closed end' is clearly defined in Figure 7 (elements 330 and 400). The capsule described by Yang does not disclose keying surfaces in these locations. Furthermore, there is no suggestion that the cap circumferential slot (3') or raised triangular slots (7) could be moved to the closed ends of the capsule, while still maintaining the locking mechanism of the capsule claimed by Yang. Therefore, Yang cannot make obvious claims 30 and 41.

Claim 43 defines the capsule of claim 41 wherein the keying surface is adapted to orient the capsule within the inhaler. Claim 44 defines the capsule of claim 41 wherein the keying surface identifies the drug to be placed in the capsule. Claim 45 defines the capsule of claim 41 comprising a keying surface on the outside of one end which is adapted to orient the capsule within the inhaler and a keying surface on the outside of the other end which identifies the drug to be placed in the capsule.

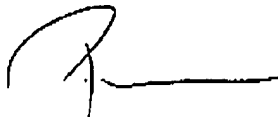
Yang does not disclose or suggest a capsule wherein the keying surfaces orient the capsule within the inhaler as in claim 43. Yang does not disclose a capsule wherein *the keying surface* identifies the drug to be placed in the capsule as in claims 44 and 45. Yang mentions that the capsule may be labeled, but suggests that the label may be placed on each half of the capsule, to be aligned when the capsule is in the final locked position (col. 2, lines 13-16).

Therefore, Yang cannot make obvious claims 43-45.

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Allowance of claims 28-30 and 41-45 is respectfully solicited.

Respectfully submitted,



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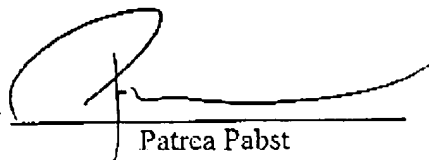
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I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, August 7, 2003, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.



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